

IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, ex rel.
MICHAEL S. LORD,

Plaintiffs/Relator,

vs.

NAPA MANAGEMENT SERVICES
CORPORATION, NORTH AMERICAN
PARTNERS IN ANESTHESIA
(PENNSYLVANIA), LLC, and
POCONO MEDICAL CENTER,

Defendants.

Civil Action No. 3:13-CV-2940

(JUDGE MANNION)

ELECTRONICALLY FILED

**REPLY OF DEFENDANTS NAPA MANAGEMENT SERVICES
CORPORATION AND NORTH AMERICAN PARTNERS IN
ANESTHESIA (PENNSYLVANIA), LLC TO PLAINTIFF’S OMNIBUS
MEMORANDUM OF LAW IN OPPOSITION TO MOTIONS TO DISMISS**

Defendants NAPA Management Services Corporation and North American Partners in Anesthesia (Pennsylvania), LLC (collectively, “NAPA”) submit this Reply in response to plaintiff Michael Lord’s (“Lord”) Omnibus Memorandum of Law in Opposition to Motions to Dismiss (“Opp.”) (Dkt. 69).

**I. LORD DOES NOT OPPOSE NAPA’S MOTION TO DISMISS
COUNTS IV-VI**

NAPA has moved to dismiss Counts IV-VI, which assert statutory claims under the Pennsylvania Whistleblower Law (Count IV) and Pennsylvania Wage Payment and Collection Law (Count V) and a common law claim for wrongful

termination (Count VI). (Dkt. 59). Lord does not oppose, or even address, NAPA's arguments for dismissing these claims in his Opposition. Thus, because NAPA's arguments are unopposed, the Court should dismiss Counts IV-VI. *See* Local Rule 7.6. *See also Cruise v. Marino*, 404 F. Supp.2d 656, 668 (M.D. Pa. 2005) (Mannion, J.) (summary judgment granted on claims plaintiff failed to address in her opposing brief); *Sikkelee v. Precision Airmotive Corp.*, No. 07-cv-886, 2011 WL 1344635, *4 (M.D. Pa. Apr. 8, 2011) (motion to dismiss certain claims deemed unopposed, and motion granted, where plaintiff failed to respond to defendants' arguments regarding those claims) (attached as **Exhibit 1**).

II. COUNTS I-II FAIL TO SATISFY RULES 12(b)(6) AND 9(b)

A. Lord Does Not Oppose the Dismissal of Counts I-II to the Extent Predicated on the Examination and Informed Consent Allegations

Counts I-II are predicated on what NAPA has labeled the (1) Immediate Availability Allegations, (2) Attestation Allegations, (3) Examination Allegations, and (4) Informed Consent Allegations. *See* NAPA's Memorandum of Law in Support of Motion to Dismiss ("NAPA Mem.") (Dkt. 59) at 7-18. Lord does not address NAPA's arguments for dismissing Counts I-II as they relate to the Examination and Informed Consent Allegations.¹ Since Lord has failed to oppose

¹ Lord's only response to NAPA's arguments regarding the Examination Allegations is the non-substantive observation that his Complaint "alleges that NAPA anesthesiologists routinely falsified physical examinations." Opp. at 17.

NAPA's arguments in any substantive way, the Court should dismiss Counts I-II to the extent predicated on the Examination and Informed Consent Allegations. *See Cruise*, 404 F. Supp.2d at 668; *Sikkelee*, 2011 WL 1344635 at *4.

B. The Immediate Availability Allegations Do Not Describe a Seven Steps Violation or Otherwise State a False Claim

Lord acknowledges that the "immediate availability" requirement of the Seven Steps regulation may be met by:

(a) a second anesthesiologist assuming temporary medical direction responsibility for the anesthesiologist providing temporary relief [to the CRNA]; (b) the relieved CRNA remaining in the immediate area so he can return immediately to the procedure; or (c) a specified anesthesiologist remaining available to provide substitute medical direction services for the anesthesiologist providing temporary relief.

Complaint ("Comp.") at ¶ 225. Despite this acknowledgement, Lord fails to allege any facts to show that these three alternatives were not met in the examples provided in his Complaint. Instead, Lord predicates his claims on the conclusory statement, asserted in each example, that the physicians who allegedly provided break relief "did not arrange adequate medical direction coverage in [their] absence." *Id.* at ¶¶ 75-81, 84-87, 89-90. This naked assertion is insufficient to establish a false claim or otherwise state plausible grounds for relief. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678, 681 (2009) (conclusory statements are not entitled to the presumption of truth); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555

(2007) (A plaintiff’s factual allegations “must be enough to raise a right to relief above a speculative level”).²

Lord contends that NAPA’s arguments regarding the Immediate Availability Allegations introduce disputed factual issues that should not be resolved on a motion to dismiss. Opp. at 11. In reality, NAPA’s arguments are based entirely on allegations included in Lord’s Complaint. The Complaint makes clear that NAPA is a group practice in which multiple physicians are on site in the operating suite at any given time. Comp. at ¶¶ 75-90, 126-27, 155-56, 163-64. It also identifies numerous instances in which NAPA physicians and CRNAs communicated by phone across operating rooms to obtain assistance. *Id.* at ¶¶ 79, 81-85, 88. Finally, the Complaint recognizes that the Seven Steps regulation can be met if another NAPA physician assumes temporary medical direction responsibility for a physician providing break coverage, or if the relieved CRNA returns immediately

² In the only example discussed in his Opposition, Lord claims that he called Dr. Marcus for assistance with extubation (the removal of the endotracheal tube used to administer general anesthesia) in October 2012, but that Dr. Marcus said he was providing a break for CRNA Shannon in another operating room. Comp. at ¶ 84. As an initial matter, assisting with extubation is not a required element of the Seven Steps regulation. *See* 42 C.F.R. § 415.110(a)(1). Moreover, instead of identifying facts to show that immediate availability could not be met through the alternative means identified in the Complaint (*see* ¶ 225), such as facts showing that no other anesthesiologists were available, Lord merely parrots the conclusion that Dr. Marcus “did not arrange adequate medical direction coverage in his absence.” Opp. at 11-12. Again, such bald assertions are not entitled to the presumption of truth. *See Iqbal*, 556 U.S. at 679.

to the procedure when asked to do so. *Id.* at ¶ 225. In short, NAPA’s arguments do not raise any speculative contentions. Rather, it is Lord’s own pleading deficiencies that prevent his claims from rising above a speculative level.

In the absence of factual allegations showing that other NAPA physicians were unavailable to provide temporary medical direction, or that the relieved CRNAs were unable to return immediately to the procedures in which they were involved, Lord’s Complaint can only raise the **possibility** of noncompliance with the Seven Steps regulation, but cannot go the extra step of showing a plausible claim for relief. *See Iqbal*, 556 U.S. at 678, 681 (“Where a complaint pleads facts that are merely consistent with a defendant’s liability, it stops short of the line between possibility and plausibility of entitlement to relief”); *Twombly*, 550 U.S. at 557-78 (something beyond the “mere possibility of loss causation must be alleged”); *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 157-58 (3d Cir. 2014) (“Describing a mere opportunity for fraud will not suffice. Sufficient facts to establish a plausible ground for relief must be alleged”).

Lord observes that defendant Pocono Medical Center (“PMC”), the facility where he worked for NAPA, is “a large hospital complex” and contends that “[e]ven if there are anesthesiologists somewhere in the hospital available to respond to an emergency, NAPA could never satisfy the [Seven Steps regulation] . . . without specifically assigning a medical directing anesthesiologist to be

immediately available at all times.” Opp. at 12 (emphasis in original). This is a disingenuous argument that ignores the many factual allegations in the Complaint which demonstrate that NAPA’s physicians worked in close proximity to one another in the PMC operating suite, and that NAPA’s doctors and CRNAs communicated with one another by phone across operating rooms to request assistance with procedures. See Comp. at ¶¶ 75-90, 126-27, 155-56, 163-64.

Lord next takes issue with NAPA’s reliance on *U.S. ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 878 (8th Cir. 2016), which found that the term “emergence” in the Seven Steps regulation is ambiguous and can reasonably be read to include a patient’s recovery in the PACU. Opp. at 14. NAPA relied on *Donegan* in arguing that Lord’s allegations failed to exclude the possibility that the physicians in his examples participated in emergence in the PACU or were present for emergence in the operating room outside the time periods Lord identified in his examples. NAPA Mem. at 12.

Lord seeks to distinguish *Donegan* by noting that the Seven Steps regulation requires both that the anesthesiologist “[r]emain physically present and available for immediate diagnosis and treatment of emergencies,” and “[p]ersonally participate[] in the most demanding aspects of the anesthesia plan, including, if applicable, induction and emergence.” Opp. at 14. Lord argues that even if emergence includes a patient’s recovery in the PACU, NAPA still could not have

billed for medical direction when the physician was not immediately available during the patient's anesthesia or failed to meet any of the other Seven Steps, "such as failing to participate in the most demanding aspects of the anesthesia plan – including extubation when a patient's airway is at greatest risk." Opp. at 14.

This argument fails for a number of reasons. First, extubation is not a procedure that a physician must perform to satisfy the Seven Steps regulation, nor does the regulation state (as Lord misleadingly suggests) that extubation is among the "most demanding aspects of the anesthesia plan" requiring anesthesiologist participation. *See* 42 C.F.R. § 415.110(a)(1). Second, while Lord is correct that the Seven Steps regulation requires the doctor to "[r]emain physically present and available for immediate diagnosis and treatment of emergencies," the Complaint does not allege that any of Lord's examples presented emergencies requiring the physicians' immediate attention. Finally, as discussed at length, Lord has failed to allege sufficient facts to show that NAPA did not satisfy the immediate availability requirement when physicians provided break coverage.

C. The Attestation Allegations Do Not Describe a Seven Steps Violation or Otherwise State a False Claim

Lord alleges that NAPA physicians pre-signed attestations in patient medical records that stated, "I was present for induction, key portions of the procedure and emergence; and immediately available throughout." Comp. at ¶ 91. He argues in his Opposition that these allegedly pre-signed attestations "were false when

signed” and remained so even if the physicians proceeded to perform all of the services attested to in the records. Opp. at 15-16. Not surprisingly, Lord fails to cite any authority to support this position.

A claim or statement is “false” when it is “objectively untrue.” *U.S. ex rel. Thomas v. Siemens AG*, 593 Fed. Appx. 139, 143 (3d Cir. 2014). There is nothing objectively false, however, about a claim based on a pre-signed attestation where the signing physician ultimately performed all of the attested-to procedures. Moreover, while the Seven Steps regulation requires physicians to document certain information in a patient’s medical record, 42 C.F.R. § 415.110(b), it does not address how that documentation is to occur or in what format. Lord fails to show why pre-signing an attestation in a patient’s medical record is somehow fraudulent, or even non-compliant with the Seven Steps, if the physician subsequently performs each of the attested-to services. Absent a false claim, Lord cannot state a viable FCA violation. *See* 31 U.S.C. §§ 3729(a)(1) & (a)(2); *U.S. ex rel. Hefner v. Hackensack Univ. Med. Ctr.*, 495 F.3d 103, 109 (3d Cir. 2007).

The Complaint provides 25 examples of allegedly pre-signed attestations, but 22 of them fail to allege (a) that the patient was a Medicare patient, (b) that NAPA submitted claims for Medicare reimbursement, or (c) that any of the claims submitted were for medically directed services. Comp. at ¶¶ 98-118, 120-22. Many of these examples also fail to identify the patients. *Id.* These examples do

not support a “strong inference” that false claims – or even any claims – were submitted to Medicare for medically directed services. *See Foglia*, 754 F.3d at 157-58. As for the three Medicare examples that Lord identifies, three instances of allegedly pre-signed attestations over the two-year course of Lord’s employment hardly constitute a fraudulent billing scheme (nor are they “material,” as discussed in Section II.D below).

NAPA does not contend, as Lord suggests (*see* Opp. at 17), that a relator must allege every instance of fraudulent conduct to adequately state a claim. To satisfy Rule 9(b), however, a relator must allege the particular details of a scheme to submit false claims – including the who, what, when, where and how of the events at issue – paired with “reliable indicia” that lead to a “strong inference” that false claims were submitted to the government. *See Foglia*, 754 F.3d at 157-58; *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1422 (3d Cir.1997). In the absence of sufficient facts showing that the purportedly pre-signed attestations related to medically directed services for Medicare patients, Lord has not adequately alleged the particular details of a fraudulent billing scheme, nor has he provided **reliable indicia** that would lead to a **strong inference** that false claims were submitted for Medicare reimbursement.

Lord contends that his allegations are enough to satisfy Rule 9(b) because the attestations were “meant specifically for Medicare reimbursement for medical

direction services.” Opp. at 16. This argument, however, fails to recognize that the attestations are part of a form completed for all patients treated by NAPA clinicians, not just Medicare beneficiaries. The Complaint states that the attestation is part of an “Anesthesia Record” used by NAPA physicians and CRNAs for “[e]ach patient” to record information about the services provided. Comp. at ¶¶ 62-63. The Complaint also alleges that the purportedly pre-signed attestations “involved all patients, **without regard to payer type.**” *Id.* at ¶ 93 (emphasis added). Clearly, the mere fact that a NAPA physician signs an attestation does not mean that the record necessarily relates to a Medicare patient.³

D. NAPA’s Alleged Seven Steps Violations Are Not Material

To be actionable, a false claim must be material to the government’s decision to pay the claim. *See Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 2002 (2016). The FCA defines “material” as “having a natural tendency to influence, or be capable of influencing, the payment or receipt

³ Lord claims that each NAPA anesthesia record includes a sticker identifying Medicare patients, and alleges that copies of these records were attached to his disclosure statement. Opp. at 17. The FCA requires the relator to serve the **government** with a copy of his complaint and “written disclosure of substantially all material evidence and information the person possesses.” 31 U.S.C. § 3730(b)(2). Lord alleges in his Complaint that he complied with this requirement and served the government with a disclosure statement. Comp. at ¶ 18. However, Lord’s disclosure statement was not filed with the Court or provided to NAPA. Lord therefore cannot rely on information purportedly included in his disclosure statement in opposing NAPA’s motion to dismiss.

of money or property.” 31 U.S.C. § 3729(b)(4). “[T]he fundamental inquiry is ‘whether a piece of information is sufficiently important to influence the behavior of [the government].’” *U.S. ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 110 (1st Cir. 2016). The materiality standard is “demanding” because the FCA is not meant to punish “garden-variety” regulatory violations. *See Escobar*, 136 S. Ct. at 2003. Materiality must also be pled with particularity. *Id.* at 2004 n. 6.

Lord claims he has adequately pled materiality by alleging (a) that NAPA improperly charged Medicare for medical direction when it should have received payment for medical supervision only, and (b) that NAPA’s Vice President of Human Resources stated in a letter to Lord that NAPA was committed to the Seven Steps regulation (a statement merely affirming NAPA’s embrace of compliance). *Opp.* at 18-19. These allegations do not come close to meeting the “demanding” materiality standard, nor do they satisfy Lord’s obligation to plead materiality with particularity. *See Escobar*, 136 S. Ct. at 2003, 2004 n. 6.

Escobar involved a legally false claim under the implied false certification theory. Thus, in order to argue that *Escobar*’s materiality analysis does not apply, Lord depicts this action as one involving factually false claims. *Opp.* at 21.

Although Lord fails to state a viable FCA case under any theory, his Complaint is

best characterized as a legally false matter under the implied certification theory.⁴ This theory of liability generally attaches where, as in this action, the defendant is alleged to have submitted a claim for payment from the government without disclosing that it failed to comply with regulations affecting its eligibility for payment. *See Wilkins*, 659 F.3d at 305. A factually false claim, in contrast, typically involves a claim that is false on its face, such as one seeking payment for services that were never provided. *See U.S. ex rel. Schimelpfenig v. Dr. Reddy's Laboratories, Ltd.*, No. 11-4607, 2017 WL 1133956, *3 (E.D. Pa. Mar. 27, 2017) (attached as **Exhibit 2**). *See also Wilkins*, 659 F.3d at 305 (holding that the court did not need to consider factual falsity, “as appellants do not contend that appellees did not deliver the services for which they sought payment”).

In any event, regardless of whether this action is construed to involve factually false or legally false claims, materiality is a necessary element that is conspicuously absent from Lord's Complaint. *See U.S. ex rel. Hill v. Univ. of*

⁴ Claims may be “factually false” or “legally false.” *See U.S. ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 305 (3d Cir. 2011). “A claim is factually false when the claimant misrepresents what goods or services that it provided to the Government.” *Id.* Alternatively, a claim is legally false when the claimant “falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment.” *Id.* A legally false claim is based on a “false certification” theory of liability. *Id.* Courts generally recognize two types of false certifications, express and implied. *Id.* Under the more expansive “implied false certification” theory, liability attaches when a claimant “makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment.” *Id.*

Med. & Dentistry, 448 Fed. Appx. 314, 317 n. 4 (3d Cir. 2011) (“Congress has . . . explicitly imposed a materiality element on claims”); *U.S. ex rel. Forcier v. Computer Scis. Corp.*, 183 F. Supp.3d 510, 523 (S.D. N.Y. 2016) (“Whether asserted on a theory of factual falsity or legal falsity, a false claim ‘must have influenced the government’s decision to pay’”).

Finally, Lord argues that the Court should not consider the 2013 guidance issued by a Medicare Administrative Contractor (“MAC”) that was attached as an exhibit to the Declaration of David M. Vaughn submitted with NAPA’s Memorandum in Support of Its Motion to Dismiss (*see* NAPA Mem. at Exhibit 1). Opp. at 19. On a motion to dismiss, however, the Court may consider matters outside the pleadings if they are a proper subject for judicial notice, such as Medicare guidance issued by local MACs. *See U.S. ex rel. Modglin v. DJO Global Inc.*, 114 F. Supp.3d 993, 1002 n. 36 (C.D. Cal. 2015); *Adams v. Luzerne County*, 36 F. Supp.3d 511, 516 (M.D. Pa. 2014).

E. Counts I-II Should Be Dismissed for Claims Before June 2011 And After June 2013

Lord worked for NAPA from June 2011 to June 2013, and filed his Complaint on December 6, 2013. *See* Comp. at 1 and ¶ 6. Although Lord alleges, on information and belief, that NAPA’s purported conduct dates back to 2007, *id.* at ¶¶ 221, 234, this allegation is clearly based on the FCA’s six-year statute of limitations, not on facts known to Lord. Indeed, the Complaint does not include a

single factual allegation regarding NAPA's pre-June 2011 conduct. The Complaint also fails to allege any facts showing that NAPA's alleged conduct continued after Lord left the organization in June 2013.

Since Lord has failed to identify any facts that would lead to a "strong inference" that NAPA submitted false claims before June 2011 or after June 2013, the Court should dismiss Counts I-II as to claims outside those dates. *See Foglia*, 754 F.3d at 157-58; *U.S. ex rel. Mastej v. Health Mgmt. Assocs., Inc.*, 591 Fed. Appx. 693, 709 (11th Cir. 2014) (FCA claims dismissed for time period after employment ended; "indicia of reliability" disappeared when plaintiff left defendants' employment and was no longer privy to information such as defendants' business practices, Medicare patients, and billing of services to Medicare).⁵

⁵ In arguing against limiting his claims to the dates of his employment, Lord cites a single allegation in his Complaint asserting that his internal reports of allegedly improper conduct "did not change [NAPA's] policies and practices." Opp. at 22; Comp. at ¶ 190. This allegation does not justify allowing Lord to pursue claims for dates beyond his employment. Indeed, Lord's argument is in stark contrast to *U.S. ex rel. Galmines v. Novartis Pharm. Corp.*, 88 F. Supp.3d 447, 457-58 (E.D. Pa. 2015), a case he cites for support, in which the court allowed the relator to amend his complaint to add new allegations involving false claims that occurred after he left his employment with the defendant. In *Galmines*, the court found that the relator had sufficiently alleged that an off-label marketing scheme had continued beyond his period of employment by pleading specific facts that illustrated through examples the continued nature of the defendant's off-label campaign. *Id.* at 458. Lord, in contrast, has failed to identify any facts showing that NAPA's purportedly improper conduct continued after he left the organization.

CONCLUSION

For the foregoing reasons, the Court should dismiss Counts I-II and IV-VI with prejudice.

Dated: May 17, 2017

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CERTIFICATE OF SERVICE

BRIAN K. FRENCH, ESQUIRE, hereby certifies that, on the 17th day of
May, 2017, he caused to be served a true and correct copy of the foregoing Reply,
by ECF, to all counsel of record.

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By: /S/ Brian K. French, Esquire
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